

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MEDTECH PRODUCTS, INC.,

Plaintiff,

v.

RANIR, LLC, et al.,

Defendants.

07 Civ. 3302 (KMK) (LMS)

MEDTECH PRODUCTS, INC.,

Plaintiff,

v.

DENTEK ORAL CARE, INC.,

Defendant.

MEDTECH PRODUCTS, INC.,

Plaintiff,

v.

POWER PRODUCTS, INC.,

Defendant.

**DEFENDANT DENTEK ORAL CARE, INC.'S
OBJECTION TO THE REPORT & RECOMMENDATION
OF CHIEF MAGISTRATE JUDGE SMITH DATED OCTOBER 11, 2007**

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Pursuant to Fed. R. Civ. P. 72(a), Defendant DenTek Oral Care, Inc. (“DenTek”) respectfully submits the following objection to the interpretation of “approximately 30% by weight vinyl acetate,” one of the disputed claim terms interpreted in the Report & Recommendation of Chief Magistrate Judge Smith dated October 11, 2007 (“Report & Recommendation”), a copy of which is attached hereto as Exhibit A. DenTek also respectfully requests that Chief Magistrate Judge Smith’s complete interpretation of the language “molding over the base” be incorporated into the construction of that phrase. DenTek further respectfully requests that the Court adopt the remaining claim constructions set forth in the Report & Recommendation, subject to any suggestions DenTek may have in response to any issues raised by Plaintiff Medtech Products, Inc. (“Medtech”).

BACKGROUND

Medtech has alleged infringement of just one patent claim in this action, Claim 17 of United States Patent No. 6,830,051 (the “’051 Patent”), a copy of which is attached hereto as Exhibit B.¹ Claim 17 of the ‘051 Patent relates to a method of fabricating a night guard device for alleviating the adverse effects of bruxism (teeth-grinding) and teeth clenching. The parties subsequently submitted briefs regarding several disputed phrases in the language of Claim 17 that required construction by the Court.

In that regard, the parties proffered differing interpretations of the phrase “having approximately 30% by weight vinyl acetate.” DenTek asserts that the phrase, taken literally, should mean “having at least 25.0% by weight vinyl acetate but not more than 33.0% by weight

¹ On October 1, 2007, the Court granted leave to Medtech to file a Second Amended Complaint. That pleading, which Medtech filed on October 4, 2007, alleges the identical patent infringement claim against DenTek.

vinyl acetate.” No broader range is expressly discussed anywhere within the four corners of the patent. Moreover, DenTek asserts that expanding the scope of the phrase, literally or by equivalents, beyond a range of 25% to 35% would leave Claim 17 insolubly ambiguous as to how much vinyl acetate could be present without infringing the claim and run contrary to the notice function of patent claims, thereby rendering indefinite the claim under the second paragraph of 35 U.S.C. § 112. *See* Def.’s Claim Construction Mem. (July 13, 2007) at 24-25; Def.’s Reply Claim Construction Mem. (July 20, 2007) at 9-10. There is simply no basis, under the intrinsic evidence, or any extrinsic evidence presented at the *Markman* hearing under which a wider range can even be argued by Medtech.

Initially, Medtech contended that the phrase should mean that “the resin has approximately 30% by weight vinyl acetate,” but then later suggested, as a compromise, that it should mean “having about, roughly, or around 30% by weight vinyl acetate.” *See* Pl.’s Claim Construction Mem. (July 13, 2007) at 20; Report & Recommendation at 21.

On September 5, 2007, Chief Magistrate Judge Smith, to whom this case was referred, held a hearing under *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996). In the Report & Recommendation, Chief Magistrate Judge Smith agreed with Medtech’s later, *i.e.*, compromise, definition for the phrase “having approximately 30% by weight vinyl acetate content.” *See* Report & Recommendation at 21-23. Chief Magistrate Judge Smith also stated that this language does not support any limitation on the breadth of the range. *See id.* at 22.

Further, Chief Magistrate Judge Smith opined that neither the phrase “approximately 30%” nor Medtech’s construction of “about, roughly or around 30%” were so ambiguous as to violate the requirements of 35 U.S.C. § 112. *See id.* Specifically, Chief Magistrate Judge Smith ruled that, “[j]ust as a person skilled in the art of resins is capable of

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determining from the commercially available resins which ones have vinyl acetate content numerically close to 30 percent and are therefore ‘approximately 30%’ by weight vinyl acetate, so a jury is capable of determining from that set of numbers which of the numbers are approximately 30. Thus, I find, and respectfully recommend that Your Honor should find, that there is no reason to incorporate a specific defined range for vinyl acetate content in Claim 17.” *Id.* at 23.

For the reasons that follow, DenTek objects to the Report & Recommendation to the extent that it finds that there is no limitation on the possible range of vinyl acetate as a matter of law, such that all possible ranges are left for application by the finder of fact. More particularly, DenTek respectfully submits that permitting a finder of fact to consider a vinyl acetate content outside a range of 25% to 35% would be impermissible as a matter of law because there is no basis to support such an interpretation and to do so would render the boundaries of the claim indeterminable and, thereby, indefinite as a matter of law.

Furthermore, DenTek respectfully submits that the construction of the disputed phrase “molding over the base” in the Report & Recommendation should incorporate Chief Magistrate Judge Smith’s complete interpretation by summarizing the reasoning and statements from page 17 of the Report & Recommendation.

ARGUMENT**I. “APPROXIMATELY 30%” CANNOT EXTEND ACROSS A RANGE THAT IS BELOW 25% OR ABOVE 35%, LITERALLY OR BY EQUIVALENTS****A. Applicable Standards of Review for Claim Construction**

Claim construction is a question of law. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996). Thus, the Report & Recommendation is subject to plenary

review by this Court. *See ACCO Brands, Inc. v. ABA Locks Mfr. Co.*, No. 06-1570, 2007 WL 2609976, at *5 (Fed. Cir. Sept. 12, 2007).

In construing a claim, three sources must be considered: the claims, the specification, and the prosecution history. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*). The *Phillips* court reaffirmed that the specification is the “single best guide” to the meaning of disputed claim language. *See id.* at 1321 (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). It continues to be proper to give the language of the claims its ordinary and customary meaning, so long as it aligns with the description of the invention in the patent. *Id.* at 1312-13 (citations omitted). “Where the specification makes clear at various points that the claimed invention is narrower than the claim language might imply, it is entirely permissible and proper to limit the claims.” *Alloc, Inc. v. Int’l Trade Comm’n*, 342 F.3d 1361, 1370 (Fed. Cir. 2003). Therefore, “[i]t is entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims.” *Phillips*, 415 F.3d at 1317.

Claims should also be construed narrowly where the boundaries are unclear to serve the notice function of claims and avoid invalidation for indefiniteness. Patent claims define the metes and bounds of the right that the patent confers on the patentee to exclude others from making, using, or selling the patented invention. *Johnson & Johnston Assocs. v. R.E. Serv. Co.*, 285 F.3d 1046, 1052 (Fed. Cir. 2002). The second paragraph of 35 U.S.C. § 112 requires the claims to particularly point out and distinctly claim the subject matter that the patentee regards as the invention. *See* 35 U.S.C. § 112, ¶ 2 (“The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.”). “Distinctly” means that the claim must have a clear and

definite meaning when construed in light of the complete patent document. *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985). The definiteness requirement guards against unreasonable advantages to the patentee and ensures that the claims give notice to the public of the extent of the legal protection afforded by the patent so that interested members of the public, including competitors of the patent, can determine whether or not they infringe. *Athletic Alternatives v. Prince Mfg.*, 73 F.3d 1573, 1581 (Fed. Cir. 1996).

To address just this problem, the law is clear that, where there is any doubt as to the propriety of two alternative constructions of the metes-and-bounds of the claim, the narrower interpretation must be taken – both to serve the notice function performed by the claims and to save the claim from invalidity under paragraph 2 of section 112. *See Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1342 (Fed. Cir. 2003) (“A claim is indefinite under § 112 ¶ 2 if it is insolubly ambiguous, and no narrowing construction can properly be adopted.”) (citations and internal quotations omitted); *Athletic Alternatives*, 73 F.3d at 1581 (“Where there is an equal choice between a broader and a narrower meaning of a claim, and there is an enabling disclosure that indicates that the applicant is at least entitled to a claim having the narrower meaning, we consider the notice function of the claim to be best served by adopting the narrower meaning.”).

B. The Report & Recommendation’s Construction of the Phrase “Approximately 30%” is Erroneous Because it Renders the Claim Insolubly Ambiguous and Indefinite

DenTek objects to the Report & Recommendation insofar as the construction of the phrase “approximately 30%” would render Claim 17 of the ‘051 Patent insolubly ambiguous as to how much vinyl acetate could be present without infringing the claim by allowing the finder of fact to consider any number falling within any range. Such fact-finding would run

contrary to the notice function of patent claims under 35 U.S.C. § 112. No finder of fact should, as a matter of law, be permitted to apply a range outside of 25% to 35% vinyl acetate.

The '051 Patent itself does not expressly define the range set by the phrase "approximately 30%." However, its specification sets the absolute minimum vinyl acetate content at 25% by weight. *See* '051 Patent, col. 5, ll. 13-16. The specification also discloses a single resin (DuPont's ELVAX®150) as exemplifying this claim limitation. *See id.*, col. 5, ll. 13-17. It is identified in the '051 Patent to be 33% vinyl acetate content by weight. *See id.*

Thus the specification expressly discloses that the phrase "approximately 30% by weight vinyl acetate" encompasses a range having a minimum of 25% by weight vinyl acetate and suggest nothing greater than 33% by weight vinyl acetate. While the Report & Recommendation notes that the patent "does not indicate that a vinyl acetate content of 33% is the highest content that can be used to make the patented invention," *see* Report & Recommendation at 21-22, significantly and tellingly, no percentage higher than 33% is ever suggested, mentioned, or identified anywhere in the patent. Furthermore, there is no principled basis upon which the range of equivalents could possibly extend beyond 35%.

To begin, the prior art of record, *e.g.*, U.S. Patent No. 6,082,363 (the "'363 Patent"; attached hereto as Exhibit C), suggests that a range of 25% to 33% was chosen to pick a preferred range that could be contrasted with the prior art. In this regard, the '363 Patent is directed to an interocclusal device with an impression preform, in which the percentage by weight of vinyl acetate is preferably greater than 33%. *See* '363 Patent, col. 5, ll. 54-56 ("In one embodiment, the third material comprises 100% of a copolymer of ethylene and vinyl acetate, and has at least 33% of vinyl acetate by weight."); *see also* Def.'s Claims Construction Mem. at 8-9. By contrast, the percentage by weight of vinyl acetate disclosed by the '051 Patent is 33%

or less (but no less than 25%). *See Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 24 (Fed. Cir. 2000) (“[C]laims should be read in a way that avoids ensnaring prior art if it is possible to do so.”) (quoting *Eastman Kodak Co. v. Goodyear Tire & Rubber Co.*, 114 F.3d 1547, 1556 (Fed. Cir. 1997)).

Furthermore, DenTek’s expert at the *Markman* hearing testified that resins having 25%, 28%, and 32% by weight vinyl acetate, as well as any other percentage between 32 and 35 (if commercially available), would constitute “approximately 30%” by weight vinyl acetate. *See* Report & Recommendation at 23. As the expert further testified, the plain language of Claim 17 of the ‘051 Patent can only be construed to encompass a range of vinyl acetate content between 25% and 35%. For example, a number less than 25%, such as 24%, is not, colloquially speaking, “approximately 30%,” but, rather, “approximately 20%.” *See id.* Similarly, a number greater than or equal to 35%, such as 36%, is not, colloquially speaking, “approximately 30%,” but, rather, “approximately 40%.” Thus, the intrinsic evidence suggests that the proper construction of the phrase “approximately 30%” covers a range from 25% to 33%, and the extrinsic evidence would, at best, suggest that the upper limit might be 35%.

Expanding the scope of the phrase “approximately 30% by weight” outside of that range would leave Claim 17 insolubly ambiguous as to how much vinyl acetate could be present without infringing the claim. The public would be left to guess as to the scope of the claim, and Medtech would be permitted to expand the scope of the claim indefinitely. Such a construction runs contrary to the notice function of a patent claim and would render it indefinite under the second paragraph of 35 U.S.C. § 112. *See Athletic Alternatives*, 73 F.3d at 1581; *Amgen*, 314 F.3d at 1342. Indeed, one of the important goals of claim construction is to interpret claims so that inventors can determine how to design products and processes that do not infringe another’s

patent. *See SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1358 (Fed. Cir. 2005) (“The ability to discern both what has been disclosed and what has been claimed is the essence of public notice. It tells the public which products or processes would infringe the patent and which would not.”), *cert. denied*, 126 S. Ct. 2887 (2006).

To the extent that Medtech purports to rely upon extrinsic evidence from its own expert to cite a wider range, that effort must fail as a matter of law. Extrinsic evidence can never be used to contradict intrinsic evidence. *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004) (“When an analysis of intrinsic evidence resolves any ambiguity in a disputed claim term, it is improper to rely on extrinsic evidence to contradict the meaning so ascertained.”) (quoting *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1367 (Fed. Cir. 2003)).² Had Medtech intended to claim a range above 35%, or below 25%, it was incumbent upon Medtech to choose claim language other than “approximately 30%.”

Definiteness problems can arise when words of degree are used in a claim. *BJ Servs. Co. v. Halliburton Energy Servs., Inc.*, 338 F.3d 1368, 1372 (Fed. Cir. 2003) (construing “about 0.06”). In these instances, the claim should be defined to correspond to what the specification discloses clearly to persons skilled in the art who want to know the actual

² Medtech’s proposed expert was not even qualified to provide testimony regarding the use and selection of resins in the manufacture of injection molded products, in that he had never (a) designed any product involving molding techniques; (b) worked with resins or their use in products; and (c) provided any advice or consultation on how to manufacture products involving resins. *See Markman* Hrg. Tr. at 221:14-229:5, 229:6-11, 232:16- 233:24 (excerpts attached hereto as Exhibit D). Although Chief Magistrate Judge Smith declined to preclude this expert’s testimony for purposes of the *Markman* hearing to construe the disputed claim language, *see id.* at 234:1-10, neither did she rely upon it, *see Report & Recommendation* at 8-9. DenTek reserves the right to move to preclude his testimony at any further proceeding in this case. In any event, the expert’s testimony contained a glaring inconsistency regarding the commercially available resins that would be suitable for manufacturing the device in accordance with the language of Claim 17 of the ‘051 Patent. *See Markman* Hrg. Tr. at 272:19-275:8.

boundaries of the patent right. For example, in *Evans Med. Ltd. v. American Cyanamid Co.*, the court noted that “the only intrinsic evidence as [to] the meaning of the terms . . . ‘about 1:1’ is the one example given in the specification, in which the ratio of the residue values of the two amino acids is 60:62 (or 0.97:1), which is to say that they are within 3% of one another.” 11 F. Supp. 2d 338, 354 (S.D.N.Y. 1998), *aff’d*, 1999 U.S. App. LEXIS 18436 (Fed. Cir. Aug. 9, 1999). Consequently, the court reasoned that, in the absence of other evidence, the construction of “about 1:1” would be determined “by the example in the specification (e.g., +/- 3%).” *Id.*³

Thus, contrary to the Report & Recommendation, *see* Report & Recommendation at 23, it is improper to leave it up to the jury to determine whether particular percentages are “approximately 30%” without any outside parameters whatsoever. The construction set forth therein provides no guidance as to the proper range of vinyl acetate content that would fall within the scope of Claim 17 because “about, roughly, or around” is synonymous in meaning with “approximately.” *See Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd.*, 476 F.3d 1321, 1326 (Fed. Cir. 2007) (construing the terms “about” and “approximately” in the same way); *see also generally* Dilworth, *About ‘about’ and Other Imprecise Claim Terms*, 78 J. Pat. & Trademark Off. Soc’y 423 (1996).

Accordingly, the language “approximately 30%” should be construed so as to permit the jury to consider a range of 25% to 33%, and perhaps consider, by equivalents, a range up to 35%, but not be permitted to consider a range below 25% or above 35%. *See Evans*, 11 F. Supp. 2d at 353. Where, as here, the claims and the specification of the ‘051 Patent fail to suggest any range other than that propounded by DenTek, the percentages stated in the body of the ‘051 Patent are the only appropriate guide for defining the boundary of Claim 17 in

³ The court then proceeded to find a range for “about 1:1” of +/- 5% only because the defendant had made a statement against interest that it could be construed as +/- 5%. *See id.*

accordance with the requirements of the second paragraph of 35 U.S.C. § 112. To interpret the phrase otherwise would untether that claim limitation from the teachings of the specification, thereby rendering the claim indefinite. *See Amgen*, 314 F.3d at 1342. Furthermore, the language the inventors chose to claim their invention – “approximately 30%” – cannot be rewritten to encompass a range that is “approximately 20%” or “approximately 40%.” *See K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1364 (Fed. Cir. 1999) (“Courts do not rewrite claims; instead, we give effect to the terms chosen by the patentee.”); *Autogiro Co. of Am. v. United States*, 384 F.2d 391, 396 (Ct. Cl. 1967) (“Courts can neither broaden nor narrow the claims to give the patentee something different than what he has set forth.”).

II. “MOLDING OVER THE BASE” SHOULD BE CLARIFIED TO INCLUDE THE REPORT & RECOMMENDATION’S COMPLETE REASONING

The Report & Recommendation interprets the disputed phrase “molding over the base” to mean

the step of injecting a thermoplastic resin, the characteristics of which are further defined in 17(b), into an occlusal mold cavity into which the base described in 17(a) has been placed so that the thermoplastic resin becomes an impression preform that *covers the space between the side walls of the base, the inner surfaces of the side walls, and the space above and on top of the horizontal surfaces of the side walls of the base.*

Report & Recommendation at 16 (emphasis added). In arriving at this definition and, in particular, the emphasized portion, Chief Magistrate Judge Smith reviewed the language of the ‘051 Patent specification and noted that “the inventor intended that the impression preform cover the entire base including the space above and on top of the horizontal side walls of the base.” *Id.* at 17. The opinion further noted in footnote 4 that the recommended construction “does not limit the creation of the bond to simply ‘contacting a heated resin with the entire upper surface of the

base,’ but instead leaves open the possibility that the unitary bond that is formed between the impression preform and the base may be achieved by any one or more of [several processes], as envisioned by the inventor.” *Id.* at 17 n.4.

Accordingly, consistent with the entirety of the reasoning underlying the recommended construction for “molding over the base,” that phrase should be clarified to mean that, however bonded, the impression preform covers the top of the entire base. Therefore, in its entirety, a complete definition would read more appropriately as follows:

the step of injecting a thermoplastic resin, the characteristics of which are further defined in 17(b), into an occlusal mold cavity into which the base described in 17(a) has been placed so that the thermoplastic resin becomes an impression preform that covers the top of the entire base, however bonded to it, including the space between the side walls of the base, the inner surfaces of the side walls, and the space above and on top of the horizontal surfaces of the side walls of the base.

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CONCLUSION

For the foregoing reasons, DenTek respectfully requests that the Court sustain the objection and amend the proposed construction to specify that the phrase “approximately 30% by weight vinyl acetate” cannot extend across a range greater than one “having at least 25% by weight vinyl acetate but not more than 35% by weight vinyl acetate,” literally or by equivalents.

DenTek further respectfully requests that the Court construe the phrase “molding over the base” to incorporate Chief Magistrate Judge Smith’s complete interpretation, to wit, that the impression preform “covers the top of the entire base, however bonded to it, including the space between the side walls of the base, the inner surfaces of the side walls, and the space above and on top of the horizontal surfaces of the side walls of the base.”

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